

REMARKS/ARGUMENTS

Status of the Claims

Claims 1-3, 7, 8, 10-18, 28-32, and 34-39 are pending in the present application. Claims 26, 27, and 33 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Claims 1(f) and 32 have been amended to recite that the nucleotide sequence encoding a *Lepidopteran* insect receptor polypeptide having *Bt* toxin binding activity is a nucleotide sequence encoding a polypeptide having the ligand binding set forth as amino acids 4038-4547 of SEQ ID NO:2. Claim 7(f) has been amended to recite a *Lepidopteran* insect receptor polypeptide comprising the ligand binding site set forth as amino acids 4038-4547 of SEQ ID NO:2. Claim 1 has further been amended to recite nucleotide sequences having at least 80% or at least 90% sequence identity with the nucleotide sequence set forth in SEQ ID NO:1, and claim 7 has been amended to recite *Lepidopteran* insect receptor polypeptides having at least 80% or at least 90% sequence identity to the amino acid sequence set forth in SEQ ID:2. Support for these amendments may be found on lines 4 and 17 of page 17 of the specification. New claims 37-39 have been added. Support for these new claims may be found in original claim 1 and lines 4 and 17 of page 17 of the specification. No new matter has been added by amendment. Reexamination and reconsideration of the claims are respectfully requested.

The Rejection Under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn

The Examiner has rejected claim 1 and dependent claims 2, 3, 7, 8, 10-18, and 32-36 on the grounds that they contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Claims 26, 27, and 33 have been cancelled without prejudice, rendering the rejection of these claims moot. It is respectfully submitted that the rejection should not be applied to the amended claims, or to new claims 37-39.

The Examiner argues that claims 1(g), 7(g), and 32 as previously amended do not meet the requirement for a written description because they do not recite nucleotide sequences encoding the entire ligand binding site of the *Lepidopteran* insect receptor polypeptide set forth

on page 35 of the specification. Applicants note that claims 1(g), 7(g), and 32 as previously amended encompass only those nucleotide sequences that have a ligand binding site and encode receptor polypeptides having *Bt* toxin binding activity. In addition, lines 5-10 of the specification provide guidance regarding the functional domains of the *Bt* toxin receptor of SEQ ID NO:2, showing the correlation between the structural and functional features of the receptor. Thus, the claims provide the relevant, identifying structural and functional characteristics of the members of each claimed genus of nucleotide sequences that distinguish them from other sequences. Accordingly, one skilled in the art would be able to determine the identity of the members of the claimed genera, and would recognize that the Applicants were in possession of the sequences recited in the claims.

Nevertheless, Applicants have amended claims 1(g), 7(g), and 32 to recite that encoded polypeptides contain the ligand binding site set forth as amino acids 4038-4547 in order to expedite prosecution. This amendment obviates the grounds for rejection set forth in the Office Action. Accordingly, it is respectfully submitted that the rejection should be withdrawn.

The Examiner that claims 7 and 8 lack sufficient written description because they recite an expression cassette encoding a polypeptide of interest. This rejection is respectfully traversed for the reasons described below.

First, Applicants note that a large number of examples of polypeptides of interest are described in the specification on line 10 of page 21 through line 16 of page 22. Furthermore, the point of novelty of the present invention is not the expression of a genus of novel polypeptides of interest. Rather, the point of novelty of the present invention is the disclosure of novel receptor polypeptides having *Bt* toxin binding activity. The *Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description Requirement,"* 66 Fed. Reg. 1099 (2001), provide that "[t]he description need only describe in detail, that which is new or not conventional." 66 Fed. Reg. at 1106, citing *Hybritech v. Monoclonal Antibodies* 231 USPQ 81 (Fed. Cir. 1986), where the court held that "a patent need not teach, and preferably omits, what is well known in the art." *Id.* at 94. In the present case, the point of novelty of claims 7 and 8 is

the novel *Bt* toxin receptor sequences comprised within the recited fusion polypeptide. The specification provides a full written description of these novel receptor sequences. Accordingly, the present claims meet the requirement for written description set forth in the *Guidelines* and the supporting case law.

In view of the above amendments, all grounds for rejection under 35 U.S.C. § 112, first paragraph, have been overcome. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

The Rejection Under 35 U.S.C. 112, Second Paragraph, Should be Withdrawn

The rejection of claims 7 and 8 under 35 U.S.C. § 112, second paragraph, on the grounds that they are ambiguous for reciting "at least one polypeptide of interest" has been maintained. This rejection is respectfully traversed for the reasons described below.

The Board of Patent Appeals and Interferences has stated that:

In rejecting a claim under the second paragraph of 35 USC 112, it is incumbent on the examiner to establish that one of ordinary skill in the pertinent art, *when reading the claims in light of the supporting specification*, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims.

Ex parte Wu, 10 USPQ2d 2031, 2033 (B.P.A.I. 1989), *emphasis added*. In the present case, no evidence or reasoning has been provided to demonstrate that the description of the phrase "polypeptide of interest" found in the specification would not allow one of ordinary skill in the pertinent art to determine the particular area set out by the claims. The specification provides that polypeptides of interest may be used to create a fusion polypeptide with the novel receptors of the invention. The specification further provides that the polypeptide of interest may be used, for example, to facilitate purification of the novel polypeptides of the invention, to provide for secretion for the novel polypeptides of the invention, or to alter the membrane localization and/or topology of the novel polypeptides of the invention (see pages 21-22 of the specification).

Thus, one of skill in the art, reading claims 7 and 8 in light of this supporting description, would be able to ascertain that the polypeptide of interest recited in these claims is a polypeptide that could be fused to the novel receptor sequences of the invention to convey a desired property to the fusion polypeptide. There are numerous examples of such polypeptides of interest in the prior art and such polypeptides are well known to those of ordinary skill in the art. Thus, contrary to the assertion made in the office action, one of skill in the art would not find the description of a polypeptide of interest in the specification to be repugnant to the meaning of this phrase. Furthermore, the claims recite only those fusion polypeptides that contain a novel receptor sequence of the invention. Therefore, the metes and bounds of the claim would be readily ascertainable by one of skill in the art.

In view of the above arguments, all grounds for the rejection under 35 U.S.C. § 112, second paragraph, have been overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

It is believed that all the rejections have been obviated or overcome and the claims are in conditions for allowance. Early notice to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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